

products may have been affected by the conduct.

In a letter received by FDA on March 10, 1995, Dr. Shainfeld notified FDA of his acquiescence to debarment, as provided for in section 306(c)(2)(B) of the act. A person subject to debarment is entitled to an opportunity for an agency hearing on disputed issues of material fact under section 306(i) of the act, but by acquiescing to debarment, Dr. Shainfeld waived his opportunity for a hearing and any contentions concerning his debarment.

II. Findings and Order

Therefore, the Deputy Commissioner for Operations, under section 306(a) of the act, and under authority delegated to him (21 CFR 5.20), finds that Dr. Fredrick Shainfeld has been convicted of a felony under Federal law for conduct: (1) Relating to the development or approval, including the process for development or approval, of a drug product (21 U.S.C. 335a(a)(2)(A)); and (2) relating to the regulation of a drug product (21 U.S.C. 335a(a)(2)(B)).

As a result of the foregoing findings and based on his notification of acquiescence, Dr. Fredrick Shainfeld is permanently debarred from providing services in any capacity to a person with an approved or pending drug product application under section 505, 507, 512, or 802 of the act (21 U.S.C. 355, 357, 360b, or 382), or under section 351 of the Public Health Service Act (42 U.S.C. 262), effective March 10, 1995, the date of notification of acquiescence (21 U.S.C. 335a(c)(1)(B) and (c)(2)(A)(ii) and 21 U.S.C. 321(dd)). Any person with an approved or pending drug product application who knowingly uses the services of Dr. Shainfeld, in any capacity, during his period of debarment, will be subject to civil money penalties. If Dr. Shainfeld, during his period of debarment, provides services in any capacity to a person with an approved or pending drug product application, he will be subject to civil money penalties. In addition, FDA will not accept or review any abbreviated new drug applications submitted by or with the assistance of Dr. Shainfeld during his period of debarment.

Any application by Dr. Shainfeld for termination of debarment under section 306(d)(4) of the act should be identified with Docket No. 95N-0280 and sent to the Dockets Management Branch (address above). All such submissions are to be filed in four copies. The public availability of information in these submissions is governed by 21 CFR 10.20(j). Publicly available submissions

may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 8, 1996.

Michael A. Friedman,

Deputy Commissioner for Operations.

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Health Care Financing Administration

Public Information Collection Requirements Submitted for Public Comment and Recommendations

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summaries of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection* Request: Reinstatement, without change, of a previously approved collection for which approval has expired; *Title of Information Collection*: Medicare and Medicaid Disclosure of Ownership and Control Interest Statement; *Form No.*: HCFA-1513; *Use*: The information provided on this form is used by State agencies and HCFA regional offices to determine whether providers meet the eligibility requirements for Titles 18 and 19 (Medicare and Medicaid) and for grants under Titles 5 and 20. Review of ownership and control is particularly necessary to prohibit ownership and control for individuals excluded under Federal Fraud statutes; *Frequency*: On Occasion; *Affected Public*: Business or other for profit, not-for-profit; *Number of Respondents*: 60,000; *Total Annual Hours*: 30,000.

2. *Type of Information Collection* Request: Extension of a currently approved collection; *Title of Information Collection*: Evaluation of the Program of All-Inclusive Care for the Elderly (PACE) Demonstration; *Form No.*: HCFA-R-165; *Use*: This survey will

collect data on functional status, service utility, and out-of-pocket costs, and satisfaction for a sample of applicants to the PACE program. This information will be to analyze the decision to participate in PACE and the impact of the program; *Frequency*: Semi-annually; *Affected Public*: Individuals and households; *Number of Respondents*: 1,833; *Total Annual Hours*: 3,745.

To obtain copies of the supporting statement for the proposed paperwork collections referenced above, access HCFA's WEB SITE ADDRESS at <http://www.ssa.gov/hcfa/hcfahp2.html>, or to obtain the supporting statement and any related forms, E-mail your request, including your address and phone number, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786-1326. Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: HCFA, Office of Financial and Human Resources, Management Planning and Analysis Staff, Attention: John Burke, Room C2-26-17, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Dated: February 16, 1996.

Kathleen B. Larson,

Director, Management Planning and Analysis Staff, Office of Financial and Human Resources, Health Care Financing Administration.

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Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Health Resources and Services Administration (HRSA) will publish periodic summaries of proposed projects being developed for submission to OMB under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, call the HRSA Reports Clearance Officer on (301) 443-1129.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including